

Core CMI for NSAIDs (*text in italics is instructional*)

This core CMI is for oral, rectal and topical dosage forms of S4 and S3 products, although some statements will not be applicable for S3.

[Medicine name][®] (*if phonetic spelling is required, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary*).

Generic name

Consumer Medicine Information

*Consumer Name
Consumer Address
Consumer Address*

Date of Dispensing

*Pharmacist Name
Pharmacist Address
Pharmacist Address*

What is in this leaflet¹

Standard information as suggested in Usability Guidelines

This leaflet answers some common questions about [Medicine name]. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits². Your doctor has weighed the risks of you taking [Medicine name] against the benefits they expect it will have for you.

Alternative:

All medicines have risks and benefits. Your doctor has weighed the risks of you taking [Medicine name] against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

¹ Depending on the length of your CMI, consider using a table of contents (see Usability Guidelines)

² Consider reversing "risks" and "benefits"

What [Medicine name] is used for

[Medicine name] relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in the following: (*as per PI*)

- different types of arthritis including rheumatoid arthritis, osteoarthritis,
- gouty arthritis and ankylosing spondylitis
- muscle and bone injuries such as sprains, strains, low back pain (lumbago), rheumatism and tendonitis, such as tennis elbow
- swelling and pain after setting broken or dislocated bones
- menstrual cramps (period pain)
- headache, including migraine
- following surgery
- dental pain

Although [Medicine name] can relieve the symptoms of pain and inflammation, it will not cure your condition. [Medicine name] belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Alternative:

[Medicine name] is used to treat the symptoms of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. Although [Medicine name] can relieve the symptoms of pain and inflammation, it will not cure your condition.

[Medicine name] belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by relieving pain and inflammation.

Non-approved uses:

Your doctor may have prescribed [Medicine name] for another reason. Ask your doctor if you have any questions about why [Medicine name] has been prescribed for you.

Use in children statement³:

[Medicine name] is not recommended for use in children (under the age of x), as there have been no studies of its effects in children.

Statement about addictive properties:

[Medicine name] is not addictive.

or

There is no evidence that [Medicine name] is addictive.

This medicine is available only with a doctor's prescription.

³ Consider this position if use in children is not a contraindication. Testing indicated that this information is more easily found under 'When you must not take it'.

Before you take [Medicine name]

or

Before you use [Medicine name]

When you must not take it When you must not use it

Do not take/use [Medicine name] if:

1. you have an allergy to:

- [Medicine name] or any of the ingredients listed at the end of this leaflet
- aspirin
- any other NSAID medicine

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking/using any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

If you are allergic to aspirin or NSAID medicines and take/use [Medicine name], these symptoms may be severe.

Pregnancy and breast-feeding⁴:

2. you are pregnant, or intend to become pregnant.

[Medicine name] may affect your developing baby if you take it during pregnancy.

3. you are breast-feeding or intend to breast-feed.

⁴ Consider including pregnancy and breast-feeding statements here or under 'Before you start to take it'.

[Medicine name] passes into breast milk and may affect your baby.

Alternative

[Medicine name] passes into breast milk. The effect on the baby is unknown.

Others, per PI:

4. you are vomiting blood or material that looks like coffee grounds.

5. you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.

6. you have a peptic ulcer (ie stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.

7. you have an inflamed rectum (back passage) or recent bleeding from the rectum.

This applies to suppositories only.

8. diarrhoea.

9. kidney disease.

10. you have or have had inflammation of the lining of the stomach or bowel.

Some examples of these conditions include Crohn's disease and ulcerative colitis.

Tampering and expiry date warnings:

Do not take/use [Medicine name] if the packaging is torn or shows signs of tampering.

Do not take/use [Medicine name] if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work (as well).

If you are not sure whether you should start taking/using [Medicine name], contact your doctor.

If use in children a contraindication:

Do not give [Medicine name] to a child under x years.

The safety and effectiveness of [Medicine name] in children have not been established.

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- any other medicines including aspirin or other NSAID medicines
- any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant.

Like most NSAID medicines, [Medicine name] is not recommended for use during pregnancy. If there is a need to consider [Medicine name] during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Alternatives:

Like most NSAID medicines, [Medicine name] is not recommended to be used during pregnancy. Your doctor will decide if you should take [Medicine name].

[Medicine name] may affect your developing baby if you take it during pregnancy. If it is necessary for you to take [Medicine name], your doctor will discuss the risks and benefits of taking it during pregnancy.

3. you are breast-feeding or plan to breast-feed.

Like most NSAID medicines, [Medicine name] is not recommended while you are breast-feeding. If there is a need to consider [Medicine name] while you are breast-feeding, your doctor will discuss with you the benefits and risks of using it.

Alternative:

[Medicine name] passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. Your doctor will

discuss the risks and benefits of taking [Medicine name] when breast-feeding.

It is not known whether [Medicine name] passes into breast milk. Your doctor will decide whether or not you should take [Medicine name].

4. you have or have had any medical conditions, especially the following:

The following is an all inclusive list for various NSAIDs. Choose those applicable to your PI.

- heartburn, indigestion, stomach ulcer or other stomach problems
- vomiting blood or bleeding from the back passage
- bowel or intestinal problems such as ulcerative colitis
- kidney or liver disease
- kidney stones
- heart failure
- high blood pressure or heart problems
- swelling of ankles or feet
- a tendency to bleed or other blood problems, such as anaemia
- diabetes mellitus or sugar diabetes
- psychiatric problems
- seizures or fits (epilepsy)
- Parkinson's disease
- asthma
- diarrhoea
- haemorrhoids (piles) or irritation of the back passage

5. you currently have an infection.

If you take [Medicine name] while you have an infection, the tablets/capsules may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.⁵

6. you plan to have surgery.

7. you are using an IUD.

If you have not told your doctor about any of the above, tell them

before you take/use any [Medicine name].

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with [Medicine name]. These include:

The following is an all inclusive list for various NSAIDs. Choose those applicable to your PI.

- aspirin, salicylates or other NSAID medicines
- warfarin, a medicine used to stop blood clots
- digoxin, a medicine used to treat heart failure
- lithium, a medicine used to treat some types of depression
- probenecid, a medicine used to treat gout
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- decongestants
- medicines that suppress the immune system
- tablets used to treat diabetes
- phenytoin, a medicine used to treat epilepsy
- certain antibiotics called sulphonamides/quinolones
- methotrexate, a medicine used to treat arthritis and some cancers
- cimetidine, a medicine used to treat ulcers

These medicines may be affected by [Medicine name], or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking [Medicine name].

Alternative:

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking/using [Medicine name] with other medicines.

How to take [Medicine name]

or

How to use [Medicine name]

This information will be product specific, consistent with the approved PI. The following order of information is suggested, but will depend upon the particular product and the amount of information. These subheadings and information are suggested but may not be necessary in all cases.

How much to take/use

Include dosage ranges, usual doses for each indication or patient group, or a general statement that the dose will depend on the patient and will be determined by the doctor.

Follow all directions given to you by your doctor and pharmacist carefully.

They/These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

Oral only:

How to take it

Including taking with water or any special precautions, if appropriate.

Swallow [Medicine name] with a glass of water.

Alternatives:

If you are taking the dispersible tablets, allow the tablets to dissolve in a glass of water, then drink it straight away.

⁵ This information is not appropriate for topical preparations.

Swallow [Medicine name] whole with a full glass of water. Do not chew them.

The tablets have a special coating to stop them dissolving until they have passed through the stomach into the bowel. Chewing them would destroy the coating.

Suppositories only:

How to use it

Your doctor will tell you how many suppositories you need to use each day.

If possible, go to the toilet and empty your bowels before using your suppository.

Suppositories work best if your bowels are empty.

Follow these steps to use a suppository:

1. Wash your hands thoroughly with soap and water.
2. Feel the suppository while it is still in the foil.
3. If it feels soft, keep it in the foil/plastic, chill it in the fridge or by holding it under cold water for a few minutes. Do not remove the foil/plastic wrapper while you are chilling it.
4. Put on a disposable glove, if desired (available from a pharmacy).
5. Remove all of the foil/plastic wrapper from the suppository.
6. Moisten the suppository by dipping it briefly in cool water.
7. Lie on your side and raise your knee to your chest.
8. Push the suppository (blunt end first) gently into your rectum (back passage).
9. Remain lying down for a few minutes so that the suppository dissolves.
10. Throw away used materials and wash your hands thoroughly.

Try not go to the toilet and open your bowels for at least an hour after using the suppository.

The suppository takes about one hour to be completely absorbed and do its work.

If you are not sure how to use a suppository, ask your doctor or pharmacist.

Topical only:

Where to use it

Use the gel only on healthy skin.

Do not put it on open wounds or injuries or on skin that has a rash or infection.

Do not put it inside the mouth or vagina.

Be careful not to get it in your eyes.

If this happens, rinse your eyes with clean water and tell your doctor.

Never swallow this medicine.

How to use it

The amount you will need will depend on the size of the painful or swollen area. Usually, an amount ranging from a cherry to a walnut will be enough.

Rub the gel gently into the skin covering the painful or swollen area. Do this 3 or 4 times each day unless you have been given other instructions. Wash your hands after rubbing it in, unless they are the area being treated.

Oral only:

When to take it

Include time with respect to food, dosing intervals, night-time dosing etc.

Take the tablets/capsules with or straight after food with a full glass of water.

This may help reduce the possibility of stomach upset.

How long to take/use it

Do not use [Medicine name] for longer than your doctor says.

Where intervals are stated in PI:

Depending on your condition, you may need [Medicine name] for a few days, a few weeks or for longer periods.

As with other NSAID medicines, if you are using [Medicine name] for arthritis, it will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis, [Medicine name] should be taken every day for as long as your doctor prescribes.

For sprains and strains, [Medicine name] is usually only needed for a few days.

For menstrual cramps (period pain), [Medicine name] is usually taken during each period as soon as the cramps begin and continued for a few days until the pain goes away.

Topical:

[Medicine name] is used for a short time only. If your symptoms do not improve after 2 weeks, or if they get worse, stop using it and tell your doctor.

If you are not sure how long to take/use your [Medicine name], talk to your doctor.

If you forget to take/use it

As per Usability Guidelines

If it is almost time for your next dose, skip the dose you missed and take/use your next dose when you are meant to.

Otherwise, take/use it as soon as you remember, and then go back to taking/using your tablets as you would normally⁶.

Do not take/use a double dose to make up for the dose that you missed.

If you have trouble remembering to take/use your medicine, ask your pharmacist for some hints.

If you take/use too much (overdose)

Immediately telephone your doctor or Poisons Information

⁶ *These two sentences are in reverse order from that recommended in the Usability Guidelines.*

Centre (telephone 13 11 26)⁷, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken/used too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention⁸. Keep these telephone numbers handy.

If you take/use too much [Medicine name], you may feel (*list symptoms in P1*)

While you are using [Medicine name]

Things you must do

If you become pregnant while taking/using [Medicine name] tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking/using [Medicine name].

Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking/using [Medicine name].

If you are going to have surgery, tell your doctor you are taking [Medicine name].

If you get an infection while using [Medicine name], tell your doctor.

[Medicine name] may hide the some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling, redness,⁹

Things you must not do

⁷ Consider including the relevant New Zealand telephone numbers here.

⁸ The reference to casualty and urgent medical attention could be left out, depending on the type of product.

⁹ Not applicable for topical preparations.

Do not give [Medicine name] to anyone else, even if they have the same condition as you.

Do not use [Medicine name] to treat any other complaints unless your doctor tells you to.¹⁰

Things to be careful of

Be careful driving or operating machinery until you know how [Medicine name] affects you. As with other NSAID medicines, [Medicine name] may cause dizziness or light-headedness in some people. Make sure you know how you react to [Medicine name] before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Things that would be helpful for your arthritis

Some self help measures suggested below may help your condition. Talk to your doctor, physiotherapist, or pharmacist about these measures and for more information.

- **Weight** - your doctor may suggest losing some weight to reduce the stress on your joints.
- **Exercise** - may be recommended by your doctor or physiotherapist to help keep or improve movement and strengthen muscles. Ask a physiotherapist for an exercise plan suited to your condition. As a general rule if any exercise hurts then do not do it.
- **Rest** - is important and is usually balanced with exercises and activity. Rest is needed when joints are hot, swollen or painful.
- **Heat** - hot showers or baths may help to ease the pain and

relax the muscles that can become tense with arthritis. Your physiotherapist or doctor can prescribe other forms of heat treatment.

- **Physical aids** - are available to help with daily household tasks. For example, there are gadgets and aids to help turn on taps, remove screw tops, pick up objects and handles can be fitted in bathrooms. Ask your doctor to give you information.

Side effects

An all inclusive list of side effects has been developed. The list does not mean all companies are disclosing the same side effects. The side effects for a particular product will depend on the Product Information and the company's disclosure policy. The list enables a consistent approach in the way the side effects are described.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking/using [Medicine name]. [Medicine name] helps most people with arthritis, but it may have unwanted side effects in a few people. If you are over 65 years of age you may have an increased chance of getting side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Alternative:

Check with your doctor as soon as possible if you have any problems while taking [Medicine name], even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, [Medicine name] can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

¹⁰ The Usability Guidelines suggest including this statement and the one above under "Before you take/use it", but consider including them here under "While you are using Medicine name".

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- dizziness, lightheadedness
- drowsiness, sleepiness
- headache
- buzzing or ringing in the ears
- sleeplessness, nightmares
- change in mood, for example, depression, restlessness, irritability
- sore or dry mouth or tongue
- hair loss or thinning
- loose nails

Topical only:

- itching, redness, swelling or blistering of the skin in the treated area

These side effects are usually mild.

or

These are the more common side effects of [Medicine name].

Tell your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- fast or irregular heartbeats, also called palpitations
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin

- signs of anaemia, such as tiredness, being short of breath, and looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- yellowing of the skin and eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal

Suppositories only:

- irritation or discomfort in the rectum (back passage) or worsening of haemorrhoids (piles)

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking [Medicine name] and tell your doctor immediately or go to casualty at your nearest hospital:

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting, seizures or fits
- pain or tightness in the chest

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

or

Some people may get other side effects while taking/using [Medicine name].

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using [Medicine name]

This information will be product specific. See general statements in Usability Guidelines, including:

Storage

Keep your tablets/suppositories in the pack/bottle until it is time to take them.

If you take the tablets/suppositories out of the pack/bottle they will not keep well.

Keep the tablets/suppositories in a cool dry place where the temperature stays below 30°C. Do not store [Medicine name] or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking/using [Medicine name] or the tablets/suppositories/gel have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

This information will be product specific. The Usability Guidelines

suggest the information should be presented in the following order:

What it looks like

Ingredients

Where Australian Food Standard codes exist, these could follow each Australian Approved name.

[Medicine name] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

Include:

- *Name and address of sponsor*
- *ARTG number*
- *Date of preparation*

The statements in this core document are optional. Some may not be appropriate for a given product. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Usability Guidelines wherever possible.